Cancer risk estimation study program in patients treated with insulin in France (GROC)

First published: 30/10/2012

Last updated: 24/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3105

Study ID

40861

DARWIN EU® study

No

Study countries

☐ France

Study description

A suspected higher risk of cancer in insulin glargine (IG) than in human insulin (HI) users was investigated in the EGB database, a permanent representative sample of the French national healthcare insurance database, over the period from January 1st, 2003 to June 30th, 2010. Methods: Cox proportional hazards time-dependent models stratified on the propensity score quartiles for use of IG vs. HI, and adjusted on insulin, biguanide and sulfonylurea possession rates were used to assess the risk of cancer or death in incident or all exclusive or predominant (≥ 80% use time) IG users compared to equivalent HI users. Results: Only type 2 diabetic patients were studied. Exposures varied from 2273 and 614 patient-years for incident exclusive IG or HI users respectively, to 3125 and 2341 patient-years for all predominant IG or HI users. All-type cancer hazard ratios (HR) with IG vs. HI ranged from 0.59 (95% confidence interval (CI) 0.28, 1.25) in incident exclusive users to 0.58 (95%CI 0.34, 1.01) in all predominant users. Cancer risk increased with exposure to insulin or sulfonylureas in these patients. Adjusted HR for death or cancer associated with IG compared to HI ranged from 0.58 (95%CI 0.32, 1.06) to 0.56 (95%CI 0.36, 0.87). Conclusion: There was no excess risk of cancer in type 2 diabetic patients on insulin glargine alone compared to human insulin alone. The overall risk of death or cancer in patients on glargine was about half that of patients on HI, thereby excluding bias from competing risk of death.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/10/2010

Study start date

Actual: 07/12/2010

Data analysis start date
Actual: 14/02/2011

Date of final study report
Actual: 20/09/2011

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Sanofi, University of Bordeaux

Study protocol

PAS Lantus 10032011.pdf(610.57 KB)

Synopsis LANTUS 06122010.pdf(777.39 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

study the posssible relationship between exposure to insulin glargine and the diagnosis of cancer

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

Medical condition to be studied

Insulin-requiring type 2 diabetes mellitus

Population studied

Short description of the study population

The study population was selected from the data available in the EGB on October 1, 2010.

The study population allowing the analysis of exposure to insulins is composed of of all EGB patients who have made at least one reimbursement request insulin between January 1, 2003 and December 31, 2009 to the National Health Insurance Fund for Salaried Workers (CNAM-TS) in Metropolitan France.

The patients included in the analysis are the patients in the study population:

– aged 18 and over;

– without ALD cancer before the first delivery of insulin;

– with at least 2 insulin deliveries during follow-up until June 30 2010;

– whose 1st issue did not take place in the same month as the death;

– without an isolated health care consumption “hole” during their exposure to insulin (patients leaving then re-entering the EGB because having changed regime, migrant, etc., i.e. at least one year without any reimbursement of care.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

5000

Study design details

Outcomes

registration for a diagnosis of cancer in diabetic patients using insulin, relationship with duration and intensity of exposure (medication possession rates) to insulin, sulfonylureas and metformin.incidence rates for individual cancer types.

Data analysis plan

Cox time-dependent risk ratio and survival analysis of cancer adjusted for propensity score for exposure to human insulin vs glargine, in various user cohorts: incident exclusive users, all exclusive users, incident predominant users, all predominant users.

Documents

Study results

LANTUS-Cohortes-Synthèse résultats-01032011.pdf(1.21 MB)

Study publications

Blin P, Lassalle R, Dureau-Pournin C, Ambrosino B, Bernard MA, Abouelfath A, Gi...

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No